



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15AHO; Docket No. CDC-2015-0031]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection for a retrospective evaluation of the prevalence of acute flaccid myelitis with MRI grey matter findings among children

aged ≤ 18 years.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0031 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy

of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Retrospective evaluation of the prevalence of acute flaccid myelitis with MRI grey matter findings among children aged ≤ 18 years - NEW - National Center for Immunization and Respiratory

Diseases, Centers for Disease Control and Prevention(CDC).

Background and Brief Description

Acute onset limb weakness, commonly referred to as acute flaccid paralysis (AFP), is a relatively uncommon syndrome among children. From August - October 2014, several clusters of AFP among children were reported from several states within the United States (U.S.) and an epidemiologic investigation was initiated to elucidate the possible causes of these cases.

CDC originally collected data under OMB Control Numbers 0920-1011 and 0920-0009. Cases were characterized by distinctive abnormalities on spinal magnetic resonance imaging (MRI), in which pathologic changes were largely restricted to the central grey matter of the spinal cord. Due to these findings and to differentiate this illness from other forms of AFP, CDC used the term 'acute flaccid myelitis' (AFM).

The main goal of this study is to obtain data in order to estimate the baseline rate of AFM that is accompanied by MRI changes confined to spinal grey matter among children ≤ 18 years of age that were seen at six pediatric medical centers in the United States. Data on spinal MRIs from years 2005-2014 will be collected from six sentinel medical centers. Physicians at these medical centers will examine the MRI reports and extract data on

specific variables using a database developed by CDC.

Data will then be sent to CDC, where 2005-2013 data will be compared with 2014 data in order to assess if 2014 rates of AFM were higher than in previous years. Furthermore, this evaluation will provide important information regarding characteristics of patients presenting with AFM and grey matter changes, assist in determining the potential for surveillance focusing on MRI findings because AFM is not routinely conducted in the United States and identify possible risk factors.

The data will be used to estimate a baseline for the rate of AFM that occurs in the United States each year. This information has not been previously collected, since the U.S. does not collect routine surveillance for AFM/AFP.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total estimated annual burden hours for the proposed project are 4,250 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Physicians	Retrospective MRI Assessment	6	8,500	5/60	4,250

	for Acute Flaccid Myelitis: Patient Summary Form				
Total					4,250

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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